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## REMARKS

### I. Status of the Claims

Claims 1-5, 7-8, 10-21, and 23-24 are pending in this application. Claims 1, 17, 20, 23, and 24 are in independent form. Claim 23 has been amended to address a minor informality.

### II. Rejections Under 35 U.S.C. § 103

All of the claims have been rejected under 35 U.S.C. § 103(a) as allegedly being obvious over U.S. 6,231,900 B1 (hereinafter “Hanke”), except for claim 19, which is rejected over Hanke in view of U.S. Patent No. 6,099,880 (hereinafter “Klacik”).

Claims 1-5, 7-8, 10-14, 17, 20 and 23-24 have been rejected as allegedly being obvious over U.S. 5,284,659 (hereinafter “Cherukuri”) in view of WO 99/59427 (hereinafter “Le”).

### III. Argument

The present invention is directed to a novel confectionery product used to promote salivation. As set forth in the pending claims, the product has two discrete regions on the surface of the product: a salivation region containing an acidulant, and an oral comfort region containing a lipid, surfactant, or mixture thereof. The relationship of the elements to the purpose of treating dry mouth (xerostomia) has been demonstrated repeatedly over the course of an extended prosecution history.

Before turning to the details of the Office Action, applicants wish to emphasize that the products described in the references do not bear any resemblance to the product described in the claims. On one hand, Hanke teaches a throat lozenge for treating sore throat caused by cough and cold. Cherukuri teaches a breath freshening

product, with ingredients that cannot even be correlated to the product described in the claims, and Le is primarily directed to a method for co-processing acid and acid sensitive ingredients to prevent the deterioration in the latter, primarily in a chewing gum. The argument that the present claims are “obvious” in view of these references is clearly not supported.

A. None of the Claims Are Obvious In View of Hanke

Hanke teaches a confectionery product for soothing sore throat and relief of symptoms associated with cough and cold (see Office Action page 3; Hanke, col. 2, lines 26-27). Hanke teaches that cooling compounds had been found to have a negative impact on flavors (Hanke, col. 1, lines 38-45), and to address the problem, the product disclosed in Hanke provides a flavor region and a cooling region which are discrete from each other and adapted to provide a different release profile for the flavor and cooling compounds, respectively (Hanke, col. 2, lines 29-31).

The Examiner alleges that the cooling region (Composition B) in Hanke reads on the claimed salivation region because it contains an acidulant. The Examiner alleges that the flavor region (Composition A) in Hanke reads on the presently claimed oral comfort region, arguing that “orange flavor” reads on the claimed oral comfort ingredient selected from the group consisting of lipids, surfactants and mixtures thereof in an amount effective to lubricate, coat or moisten the oral cavity (Office Action, page 5). This is based on the incorrect understanding of the composition and functionality of orange flavor oil mentioned in Hanke as an example of orange flavor.

As evidenced in the Declaration of Kevin Stanton submitted herewith, orange flavor oil and essential oils in general are not “lipids” as used in the present claims

and as that term would be understood by one of ordinary skill in the art. Lipids, as that term would be understood by one of ordinary skill in the art, generally refers to glycerol esters of fatty acids, which account for ninety-nine percent of lipids of plant and animal origin. *See* Owen R. Fennema, Ed., *Food Chemistry*, Marcel Dekker, Inc. (New York) (1985), p.140. Orange flavor oil on the other hand is a so-called “essential oil” which, contains terpenes, alcohols, aldehydes, ketones and esters. Therefore the Examiner is incorrect that orange flavor oil is a lipid, as described in the present application.

Orange flavor oil does not lubricate, coat or moisten the oral cavity to provide oral comfort as presently claimed. To the contrary, as shown in the attached Materials and Safety Data Sheet (MSDS) for orange flavor oil, and as attested to in the attached Declaration of Kevin Stanton, orange flavor oil is an irritant, and would not be used as an oral comfort ingredient, as this is not an inherent property of orange oil, as is incorrectly asserted by the Examiner. This understanding by one of ordinary skill in the art is clear and unequivocal based on the completely different chemical composition of essential oil versus lipids. Thus, Hanke does not disclose an oral comfort ingredient selected from the group consisting of lipids, surfactants and mixtures thereof.

Turning to claim 20, directed to a method for treating xerostomia, or dry mouth, Hanke does not disclose such a method, inherently or otherwise. Hanke discloses a confectionery product “suitable for the relief of cough and cold like symptoms” (col. 2, lines 27-29), which are not the same as drymouth symptoms. Hanke makes references to “sore throats and the relief of other symptoms of coughs and colds” (col. 1, lines 11-12). A sore throat due to cold is not “a symptom of dry mouth.” In fact, the Office Action refers to “throat irritation,” which phrase does not appear in Hanke; the reference uses the

phrase “sore throat”. In summary, the Office Action is incorrect as a factual matter where it states at page 7 that the confectionery according to Hanke is administered to “the same population (those with throat irritation, which is a symptom of xerostomia).”

To further illustrate that a method of treating cough and cold is distinct from a method of treating dry mouth, attached is a brochure from the National Institutes of Health, entitled “Dry Mouth” (**Tab A**). This document shows that xerostomia is its own recognized indication, distinct from cough and cold. As noted in the Declaration of Kevin Stanton submitted herewith, the product according to the present claims was developed to address dry mouth, which is clearly distinguishable from a treatment for cough or cold. Insofar as the rejection relies on a parallel between a treatment of cough and cold symptoms and treatment of dry mouth, it is respectfully requested that the rejection be reconsidered and withdrawn.

**B. Klacik Does Not Overcome the Deficiencies of Hanke**

Klacik is applied in combination with Hanke against Claim 19. Whatever the merits of Klacik with respect to the mold limitation, the secondary reference does not disclose the elements of independent Claim 17, discussed above. Specifically, Klacik does not teach an acidulent concentrated in a salivation region discrete from an oral comfort region containing a lipid, surfactant or mixture thereof.

**C. The Claims Are Not Obvious in View of Cherukuri and Le**

Cherukuri is directed to a breath freshening product which uses a salt as a breath deodorizer. Le, on the other hand, is directed to a method for modulating the acidity of a product by coprocessing acid and acid sensitive ingredients. The Cherukuri and Le references clearly do not teach the elements as alleged in the Office Action, and

clearly there is no motivation to combine them in the manner proposed by the Examiner. In particular there is no hint in either reference to form a salivation-enhancing product with separate regions on the surface of the product containing an acidulant and a lipid and/or surfactant, respectively. Moreover, there is no hint of the benefits achieved through a product having the composition and structure of the present invention.

With respect to Cherukuri, the absence of a salivation agent in that reference was argued in an interview conducted on February 17, 2005, and it was agreed that limiting the salivation ingredient to an acidulant (as has been done in all the claims) overcame Cherukuri as a reference. However, rather than reducing the number of issues for consideration, the Examiner now alleges that even with this element (the acidulant) entirely absent from the primary reference, it would have been obvious to substitute an acidulant from another reference, Le, for “reasons” that bear no relation to the subject invention or to the teaching of either references. This is improper, Cherukuri does not disclose an acidulant concentrated in a discrete region, and there is no valid motivation to import the ingredient from Le.

According to the Office Action, page 10, Cherukuri Table II, Example III, describes a possible composition for the “shell” component. The “shell” component, is said to “read on” the salivation region, once the “bio effecting agent” disclosed in Cherukuri is replaced with an acidulant, according to a motivation purportedly found in the secondary reference, Le (Office Action pages 11-12). Likewise, the core component is alleged to “read on” the claimed oral comfort region, apparently because the fat encapsulation in the “core” region, as taught in Table I (col. 12), contains one or more lipids or surfactants.

Cherukuri does not teach that the fat encapsulation is present in an amount effective to coat or moisten the oral cavity. Likewise, Cherukuri does not teach the presence of an acidulant to enhance salivation. Neither reference teaches or suggests that breath deodorant, disclosed in the “shell” region of Cherukuri is a bio effecting agent which could be substituted with an acidulant. It is impossible to arrive at the claimed invention from this starting point.

The essential teaching of Le is that acidulant is coprocessed with acid sensitive components according to a particular method and evenly distributed in the product, to prevent degradation of acid-sensitive components. This was pointed out after Le was first applied in a rejection in November, 2001, and it was pointed out how this was distinguished from the claimed concept of a confectionery product wherein the acid component is concentrated in a macroscopic region(s) of the product to promote salivation. The issue was acknowledged in an Examiner’s Interview Summary dated December 16, 2002, and thereafter, when the application was refiled, the rejection over Le was dropped. Aside from being incorrect for the reasons set forth above, it is inappropriate in light of M.P.E.P. 707.07(g), to cite these references as support for an even more general proposition, as it amounts to piecemeal examination.

Le does not teach or provide any suggestion to concentrate acidulant in one region of a product, or to combine a salivation region in a product configuration having a separate oral comfort region, for the purpose of promoting salivation (or for any other purpose). In fact, Le teaches away, in the sense that the co-processed composition is homogeneously distributed throughout the product to protect the acid sensitive components. The Examiner relies on Le as teaching the use of acidulant “for a variety of

reasons”, including increasing saliva in the mouth (Office Action, page 11). From the Office Action, it is not clear which of these reasons would lead one of ordinary skill in the art to concentrate the acidulent in one region of the product in order to create a confectionery product that can be used to treat xerostomia, for example. The purported motivation to combine Le with Cherukuri is given in the Office Action as follows:

a skilled artisan would have been motivated to utilize an acidulent in Cherukuri’s example as the bio-effecting agent in place of the breath freshener if one desired to treat xerostomia and dry mouth rather than halitosis. Secondly, one would have been motivated to utilize an acidulent in the shell portion since Cherukuri teaches the shell portion provides the release of the first flavor (the rapid release portion) and thus a skilled artisan would have been motivated to utilize an acidulent in the shell portion since Le teaches acidulents are conventionally utilized to improve and enhance the release of flavor.

What this boils down to is that Le teaches that acidulents are known for a variety of purposes, and the Examiner considers it obvious to concentrate that ingredient in a particular portion of an unrelated confectionery product for any of those reasons. That does not meet the standard of obviousness enunciated by the Federal Circuit. Indeed, “if one desired to treat xerostomia and dry mouth rather than halitosis,” as the Examiner suggests, one would not have started with the prior art relied upon by the Examiner to make the rejection.

It should be noted further that Cherukuri discloses discrete regions on a surface of a product only as an alternative embodiment, and the compositions of the “shell” and “core” that the Examiner relies upon are directed to that embodiment. According to one embodiment of Cherukuri, the regions may each have a surface on the

exterior of the product, as shown in Fig. 6.<sup>1</sup> However, the compositions that are taught in the specification are for a product in which one region is encapsulated in another.

It is respectfully requested that the rejection be reconsidered, and in particular that the Examiner take a fresh look at whether there is in fact sufficient motivation in Le to concentrate an acidulant in a particular region of a product taught (but not exemplified) in a particular embodiment of Cherukuri, or whether that motivation relies on impermissible hindsight. Applicants submit that there is insufficient motivation to concentrate acidulant in a macroscopic portion of a product based on the teaching of Le.

For the foregoing reasons, it is believed that the claims are allowable over the art of record.

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<sup>1</sup> According to Cherukuri at col. 11, lines 29 to 43, and in the brief description of the drawings, there are two embodiments: one in which a shell substantially envelopes a core, as shown in Figs. 3 and 4, and another as shown in Figs. 5 and 6, where there is no “core”. The reference to “Figs. 3-5” at col. 11, line 29 is an error, because Figs. 5 and 6 are the same embodiment (Fig. 6 is the cross-sectional view of Fig. 5). Fig. 6 does not depict a shell and a core. The Examples are compositions used in the preferred “shell” and “core” embodiment, not the embodiment of Fig. 6.

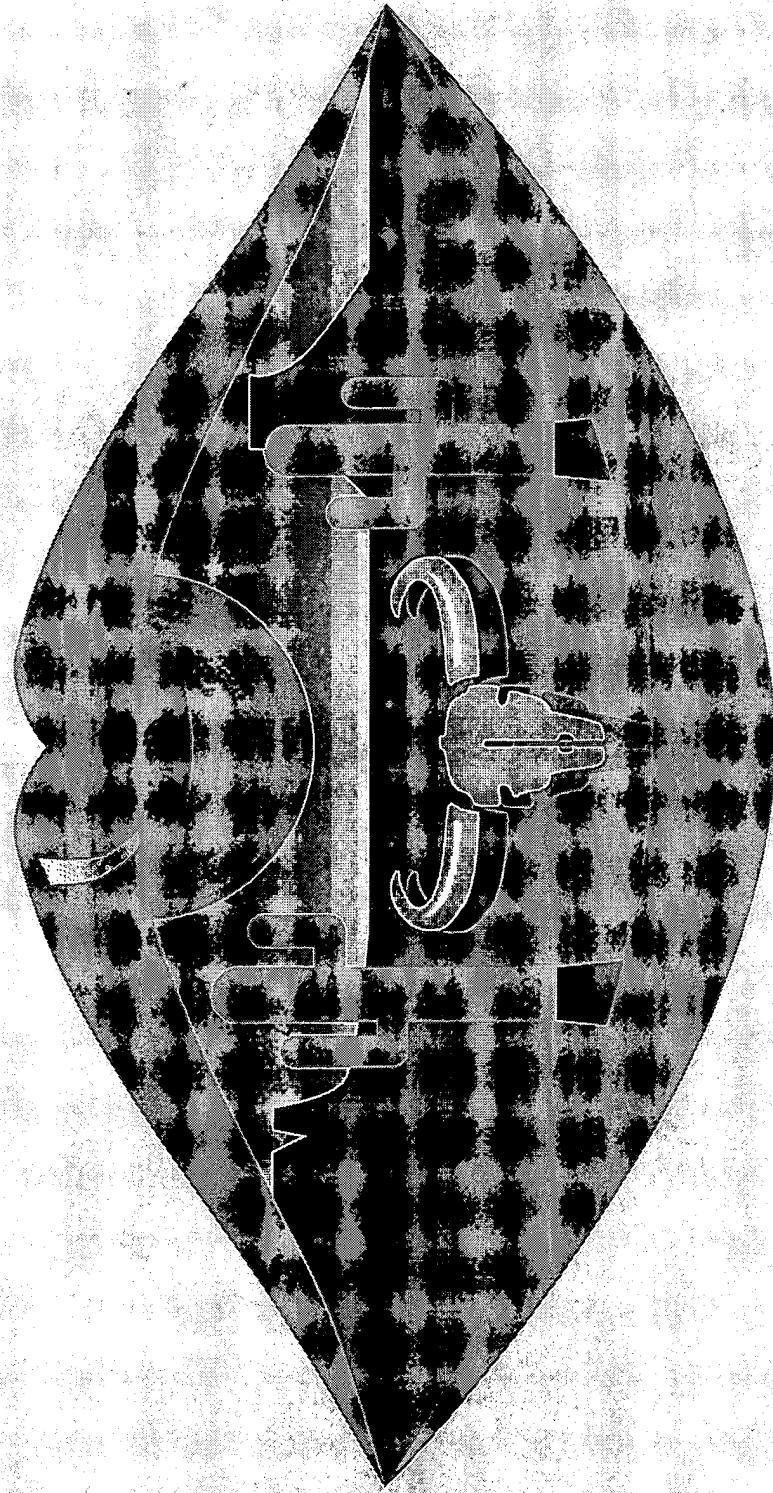
Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

  
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# DRY MOUTH



NATIONAL INSTITUTES OF HEALTH • National Institute of Dental and Craniofacial Research

## WHAT DO I NEED TO KNOW ABOUT DRY MOUTH?

Everyone has a dry mouth once in a while—if they are nervous, upset or under stress.

But if you have a dry mouth all or most of the time, it can be uncomfortable and can lead to serious health problems.

### DRY MOUTH...

- can cause difficulties in tasting, chewing, swallowing, and speaking
- can increase your chance of developing dental decay and other infections in the mouth
- can be a sign of certain diseases and conditions
- can be caused by certain medications or medical treatments

Dry mouth is not a normal part of aging. So if you think you have dry mouth, see your dentist or physician—there are things you can do to get relief.

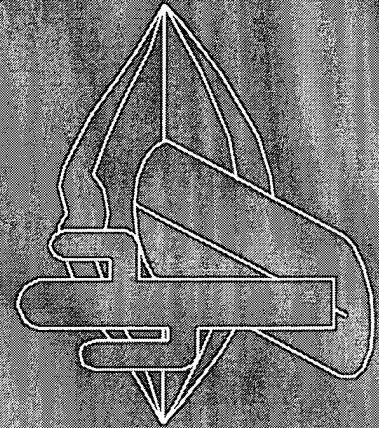
### WHAT IS DRY MOUTH?

Dry mouth is the condition of not having enough saliva, or spit, to keep your mouth wet.

### SYMPTOMS INCLUDE:

- a sticky, dry feeling in the mouth
- trouble chewing, swallowing, tasting, or speaking
- a burning feeling in the mouth
- a dry feeling in the throat
- cracked lips
- a dry, tough tongue
- mouth sores
- an infection in the mouth

*The technical term for dry mouth is xerostomia (ZEE-oh-STOH-mee-ah)*



*Some people feel they  
have a dry mouth even if  
their salivary glands are  
working correctly. People  
with certain disorders,  
like Alzheimer's disease*

*or those who have  
suffered a stroke, may not  
be able to feel wellness in  
their mouth and may  
think their mouth is dry  
even though it is not.*

#### WHY IS SALIVA SO IMPORTANT?

Saliva does more than keep the mouth wet.

- It helps digest food
- It protects teeth from decay
- It prevents infection by controlling bacteria and fungi in the mouth

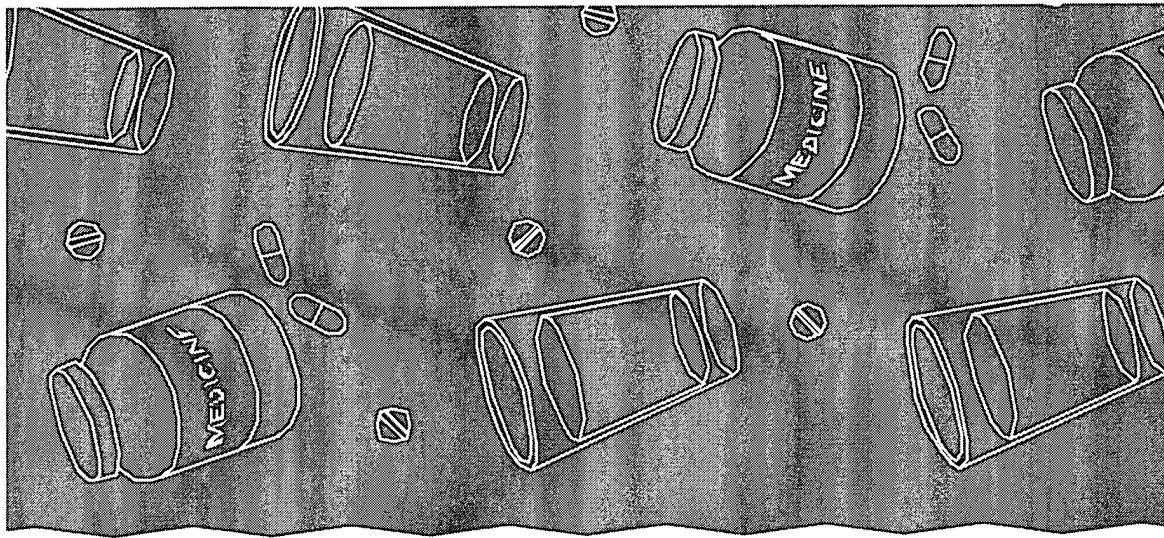
- It makes it possible for you to chew and swallow

Without enough saliva you can develop tooth decay or other infections in the mouth. You also might not get the nutrients you need if you cannot chew and swallow certain foods.

#### WHAT CAUSES DRY MOUTH?

People get dry mouth when the glands in the mouth that make saliva are not working properly. Because of this, there might not be enough saliva to keep your mouth wet. There are several reasons why these glands (called salivary glands) might not work right.

• **Side effects of some medicines.** More than 400 medicines can cause the salivary glands to make less saliva. Medicines for high blood pressure and depression often cause dry mouth.



- **Disease.** Some diseases affect the salivary glands. Sjögren's Syndrome, HIV/AIDS, diabetes, and Parkinson's disease can all cause dry mouth.
- **Radiation therapy.** The salivary glands can be damaged if they are exposed to radiation during cancer treatment.
- **Chemotherapy.** Drugs used to treat cancer can make saliva thicker, causing the mouth to feel dry.
- **Nerve Damage.** Injury to the head or neck can damage the nerves that tell salivary glands to make saliva.

#### WHAT CAN BE DONE ABOUT DRY MOUTH?

Dry mouth treatment will depend on what is causing the problem. If you think you have dry mouth, see your dentist or physician. He or she can try to determine what is causing your dry mouth.

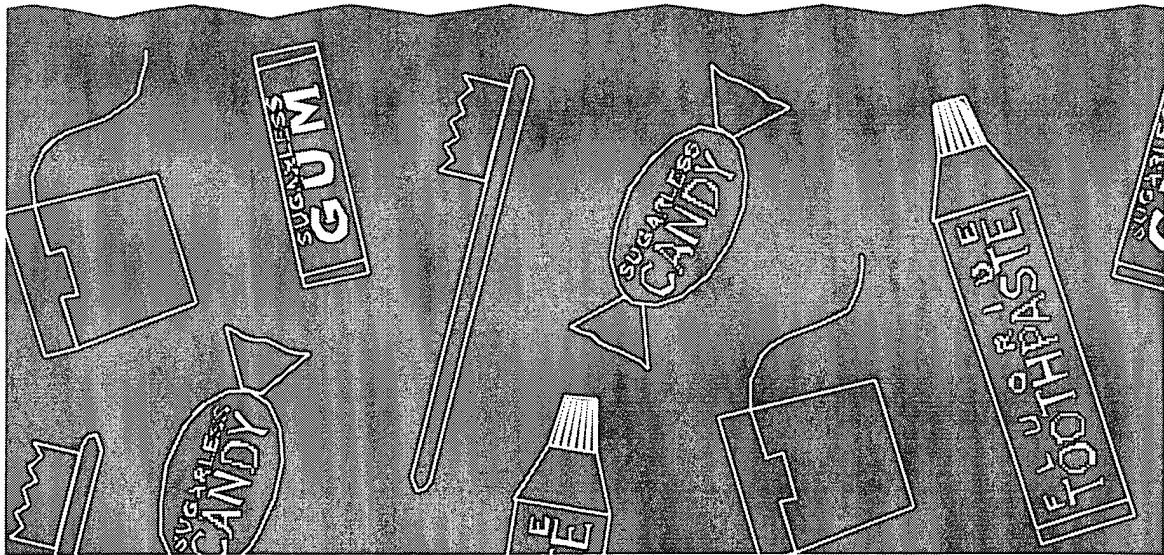
- If your dry mouth is caused by medicine, your physician might change your medicine or adjust the dosage.
- If your salivary glands are not working right but can still produce some saliva, your physician or dentist might give you a medicine that helps the glands work better.
- Your physician or dentist might suggest that you use artificial saliva to keep your mouth wet.

### WHAT CAN I DO?

- Sip water or sugarless drinks often.
- Avoid drinks with caffeine, such as coffee, tea, and some sodas. Caffeine can dry out the mouth.
- Sip water or a sugarless drink during meals. This will make chewing and swallowing easier. It may also improve the taste of food.
- Chew sugarless gum or suck on sugarless hard candy to stimulate saliva flow; citrus, cinnamon or mint-flavored candies are good choices.
- Don't use tobacco or alcohol. They dry out the mouth.
- Be aware that spicy or salty foods may cause pain in a dry mouth.
- Use a humidifier at night.

Remember, if you have dry mouth, you need to be extra careful to keep your teeth healthy. Make sure you:

- Gently brush your teeth at least twice a day.
- Floss your teeth every day.
- Use toothpaste with fluoride in it. Most toothpastes sold at grocery and drug stores have fluoride in them.
- Avoid sticky, sugary foods. If you do eat them, brush immediately afterwards.
- Visit your dentist for a check-up at least twice a year. Your dentist might give you a special fluoride solution that you can rinse with to help keep your teeth healthy.



### TIPS FOR KEEPING YOUR TEETH HEALTHY

Remember, if you have dry mouth, you need to be extra careful to keep your teeth healthy. Make sure you:

FOR MORE INFORMATION  
ON SJÖGREN'S SYNDROME

FOR ADDITIONAL COPIES  
OF THIS BOOKLET  
CONTACT:

Sjögren's Syndrome is a major  
cause of dry mouth. You can get infor-  
mation about dry mouth related to  
Sjögren's Syndrome from:

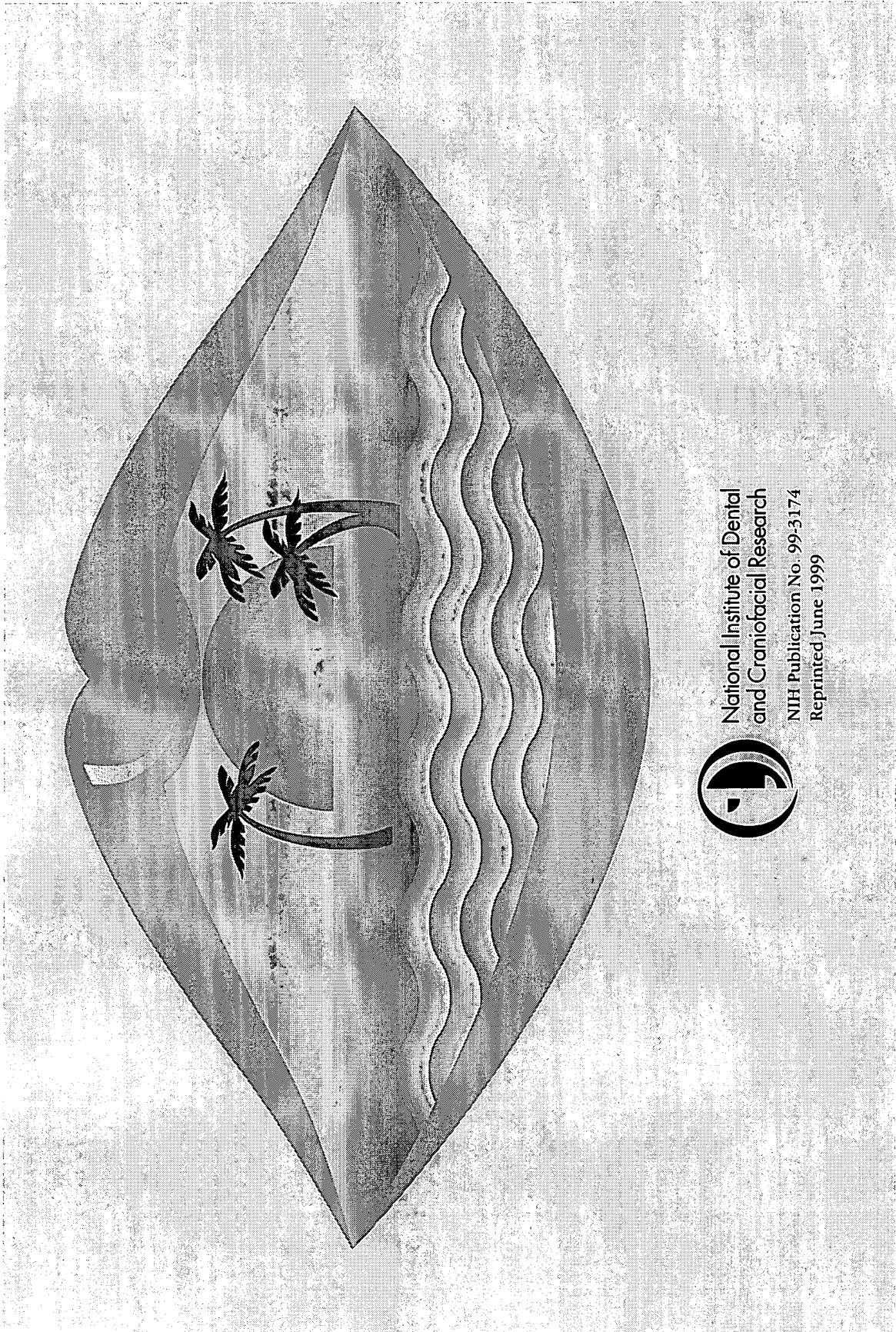
Sjögren's Syndrome Clinic  
National Institute of Dental  
and Craniofacial Research  
Building 10, Room 1N113  
10 Center Drive MSC 1190  
Bethesda, MD 20892-1190  
Tel: 301-435-8528

[http://wwwdir.nidcr.nih.gov/dirweb/  
gtib/sjogrens/SjogrenIndex.asp](http://wwwdir.nidcr.nih.gov/dirweb/gtib/sjogrens/SjogrenIndex.asp)

National Oral Health Information  
Clearinghouse  
1 NOHIC Way  
Bethesda, Maryland 20892-3500  
Tel: (301) 402-7364

Sjögren's Syndrome Foundation,  
Inc.

8120 Woodmont Avenue, Suite 530  
Bethesda, MD 20814  
Tel: 301-718-0300 or 800-475-6473  
<http://www.sjogrens.org>



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